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REGULATING BIOPHARMACEUTICAL INNOVATION

INTENSIVE COURSE

Distinguished Visiting Professor Rebecca Eisenberg

Faculty of Law

University of Toronto

2004

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Regulating Biopharmaceutical Innovation

Course Readings (updated statutory provisions to follow in a separate supplement)

Professor Rebecca S. Eisenberg, University of Michigan Law School

University of Toronto, February 3-12, 2004

Tuesday, February 3, 6:10-8:30 p.m., *FDA regulation of new drugs*:

- Excerpts from FDA CDER, *From Test Tube to Patient: Improving Health Through Human Drugs*
- Rebecca S. Eisenberg, *Reexamining Drug Regulation From the Perspective of Innovation Policy*
- U.S. Federal Food, Drug & Cosmetic Act §§ 505 [21 U.S.C. §§ 355](a), (b)(1), (b)(4), (c)(1), (c)(2), (d), (e)

Wednesday, February 4, 12:10-2:00 p.m., *Patenting biopharmaceutical inventions*:

- In re Brana
- University of Rochester v. G.D. Searle
- Schering Corp. v. Geneva
- Geneva v. Glaxosmithkline
- Fisons v. Quigg
- Astra v. Lehman
- Hoechst-Roussel v. Lehman
- U.S. Patent Act (35 U.S.C.) §§ 101, 102, 103, 112, 121, 156

Thursday, February 5, 12:10-2:00 p.m., *FDA-administered exclusive rights (Orphan Drug Act, pediatric exclusivity, new chemical entities, new clinical investigations)*:

- Berlex v. FDA
- Baker Norton v. FDA
- Sigma-Tau Pharmaceuticals v. Schwetz
- National Pharmaceutical Alliance v. Henney
- FDA CDER, *Frequently Asked Questions for New Drug Product Exclusivity*
- Bristol-Myers-Squibb v. Shalala; Upjohn v. Kessler
- U.S. Federal Food, Drug & Cosmetic Act §§ 525-528 [21 U.S.C. §§ 360aa-dd], 505A [21 U.S.C. § 355a], 505 [21 U.S.C. § 355](j)(5)(D)

Monday, February 9, 12:10-2:00 p.m., *Patent enforcement; ANDA litigation*:

- Integra Lifesciences I, Ltd. v. Merck KgaA
- Bayer v. Elan; Bayer AG v. Biovail
- Zenith v. Bristol-Myers Squibb
- Warner-Lambert v. Apotex
- U.S. Patent Act (35 U.S.C.) §§ 156, 271; Federal Food, Drug & Cosmetic Act §§ 505(b)(2), (b)(3)

Tuesday, February 10, 6:10-8:10 p.m., *ANDAs, Orange Book; Generic exclusivity*:

- Zeneca v. Shalala
- Apotex v. Thompson
- Purepac v. Friedman
- FDA CDER, *180-Day Generic Exclusivity*

Wednesday, February 11, 4:10-6:30, *Antitrust considerations and regulatory reform*:

- In re Cardizem CD Antitrust Litigation
- Valley Drug Co. v. Geneva Pharmaceuticals, Inc.
- FDA, *Applications for FDA Approval To Market A New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of ANDAs Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed; Final Rule*
- Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Title XI, Subtitle A - Access to Affordable Pharmaceuticals and Subtitle B - Federal Trade Commission Review

Thursday, February 12, 12:10-2:00 p.m., *International considerations*:

- FDA Office of Regulatory Affairs Regulatory Procedures Manual, Coverage of Personal Importations
- Patented Medicine Prices Review Board (Canada), *Drug Patents and Drug Prices: The Role of the PMPRB*
- U.S. v. Rx Depot
- Letters from FDA to Robert P. Lombardi and Gregory Gonot
- Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Title XI, Subtitle C - Importation of Prescription Drugs